

F. Appeals of Scientific Review

1. Consultation. The ~~applicant~~PI/PD should carefully examine the review report provided by CIRM. Any questions about the conduct of the review must first be raised with the SRO responsible for the review meeting in question. The SRO can discuss the ~~applicant's~~PI/PD's concerns, answer any questions, and explain the appeals process. Once the ~~applicant~~PI/PD has conferred with the SRO, CIRM will accept a request for appeal.

2. Grounds. Grounds for appeal are strictly limited to circumstances in which ~~an applicant~~a PI/PD can show that a reviewer's demonstrable financial, professional or personal -conflict of interest (as defined in Cal. Code Regs., Title 17, section 100003) had a negative impact on the review process and resulted in a flawed review. This shall be the only ground for appeal. Differences of scientific opinion between or among PIs and reviewers are not grounds for appeal.

3. Written Appeal. To lodge an appeal, the ~~applicant~~PI/PD must submit a written request to the SRO ~~or to the Chief Scientific Officer~~ within 30 days from the date that CIRM makes the review report available to the ~~applicant~~. ~~CIRM staff will then assess the merits of the PI/PD.~~ The written request should identify the alleged conflict(s) of interest (with reference to the definitions found in as defined in Cal. Code Regs., Title 17, section 100003) and clearly state the facts that demonstrate the conflict of interest.

4. Decision. ~~CIRM staff will assess the written appeal in consultation with the Chair and both Vice-Chair(s) of the GWG, and present a written recommendation to the President of CIRM. If the Chair of the GWG has a financial, professional or personal conflict of interest (as defined in Cal. Code Regs., Title 17, section 100003) in the Application that is the subject of the appeal, staff will consult with an eligible scientific member of the GWG (i.e., a member who has no financial, professional or personal conflict of interest)—) selected by the President of CIRM. (Scientific members are those described in Health & Safety Code section 125290.60(a)(2).) If the one Vice-Chair(s) of the GWG has a conflict of interest in the Application (as defined in Health & Safety Code section 125290.30(g)), staff will consult with the other Vice-Chair. If both Vice-Chairs have conflicts of interest, staff will consult with an eligible patient advocate member of the GWG (i.e., a member who has no conflict of interest). The President of CIRM will consider the appeal and the recommendations and issue a final written decision on the merits of) selected by the President. (Patient advocate members are those described in Health & Safety Code section 125290.60(a)(1).) The President will then consider the appeal and the recommendations. If the President concludes that the above-stated grounds for appeal have been established, the President will order a new review of the application, as described below. The President's decision will be communicated to the PI/PD in writing.~~

5. New Review. If an appeal is meritorious, the Application will receive a new

review by the following a subcommittee consisting of three scientific members of the GWG: (1) the Chair of the GWG; (2) the Vice Chair(s) of the GWG; (3) at least two, but no more than three, scientific reviewers of the GWG or specialists selected by CIRM staff in consultation with the chair of the GWG; and (4) if the Application is for disease-specific research, the patient advocate member of the GWG who was appointed from an advocacy group for that disease, provided that he or she is eligible to participate. three patient advocate members of the GWG, all selected by the President, as stated below. The subcommittee will review the application in accordance with the GWG review procedure set out in Health & Safety Code section 125290.60(c).

~~If any of the members in categories (1) through (3) above has a conflict of interest in the Application under the applicable conflict of interest policies, staff shall select an eligible scientific or patient advocate member, as appropriate, to serve in his or her place. Members in categories (2) and (4) above may waive their participation, or if they do not have a conflict of interest in the Application, designate another eligible patient advocate member of the GWG to participate in their place.~~ a. Scientific Members. For the three scientific members, the President will first invite the Chair of the GWG, followed by whichever additional scientific members the President selects. A scientific member with a conflict of interest (as defined in 17 CCR § 100003) may not participate.

~~CIRM staff, in consultation with the members in categories (1) through (4) above, will set a date for the review. At least two weeks before the scheduled review, all eligible patient advocate members of the GWG will be invited to participate. The Application will be reviewed pursuant to the procedures for the review of Applications set forth in the GWG bylaws, provided, however, that the quorum requirements shall not apply. A summary of the new review and recommendation will be submitted to the ICOC, which will make the final decision on funding the Application in question.~~ b. Patient Advocate Members. For the patient advocate members, the President will invite both Vice-Chairs. If, in the view of the President, the Application is for research that is specific to a disease for which a patient advocate has been appointed to the ICOC, that patient advocate will also be invited to participate. If fewer than three of the above choose to participate, the President may select additional patient advocate members, for a total of three patient advocate members. A patient advocate member with a conflict of interest (as defined in Health & Safety Code §125290.30(g)) may not participate.